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CM1737

(12) **UK Patent Application** (19) **GB** (11) **2 273 673** (13) **A**

(43) Date of A Publication 29.06.1994

(21) Application No 9226691.5

(22) Date of Filing 22.12.1992

(71) Applicant(s)
Unilever Plc

(Incorporated in the United Kingdom)

**Unilever House, Blackfriars, LONDON, EC4P 4BQ,
United Kingdom**

(72) Inventor(s)
**Michael Richard Lowry
Philip Christopher Waterfield**

(74) Agent and/or Address for Service
**R J Tonge
Unilever Plc, Patent Division, Colworth House,
Sharnbrook, BEDFORD, MK44 1LQ, United Kingdom**

(51) INT CL⁵
B05B 5/025 , A61K 7/16 , A61M 11/00

(52) UK CL (Edition M)
**B2F FGB F120
A5B BZ B822 B823 B825**

(56) Documents Cited
None

(58) Field of Search
**UK CL (Edition L) A5B BZ ; B2F FGB
INT CL⁵ A61K , A61M
ONLINE DATABASE: WPI**

(54) **Dental active delivery system**

(57) A dental active material such as a fluoride is delivered to the oral cavity by electrostatic spraying. The dental active material can be sprayed at ultra-low flow rates.

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Fig.1.

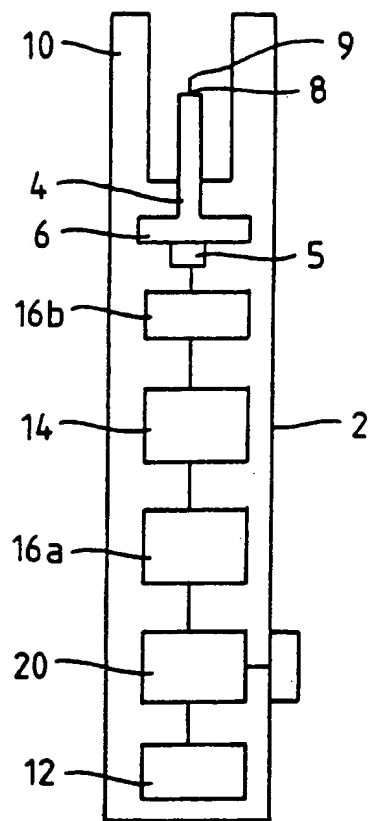
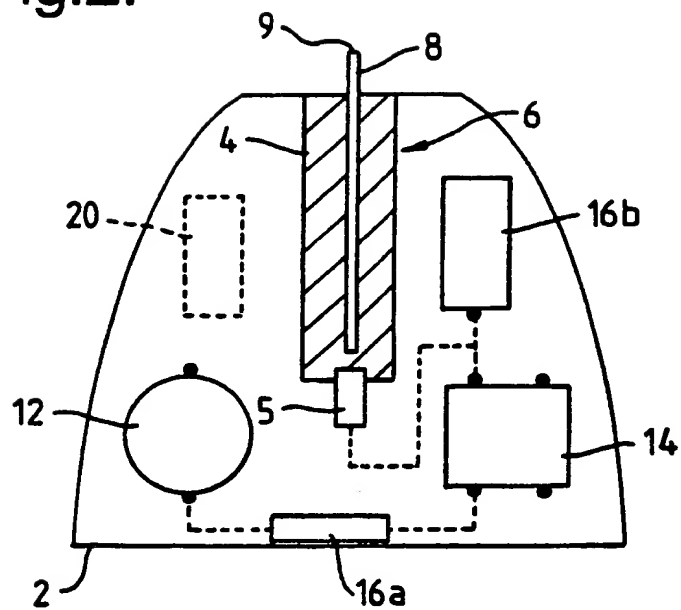


Fig.2.



- 1 -

DENTAL ACTIVE DELIVERY SYSTEM

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This application relates to a system for delivering dental active materials to the mouth. More particularly the invention relates to methods and apparatus for applying such materials to the oral cavity using the principle of electrostatic spraying. The invention is particularly useful for delivering dental active materials which require delivery in very small quantities.

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Conventionally dental active materials are applied to the oral cavity either by incorporating them into general oral cleansing compositions, such as toothpastes or mouthwashes, or by incorporating them into a cosmetically acceptable base such as a cream or gel. This may then be rubbed into the effected area in the mouth.

15

20

A problem with delivery of such materials from oral cleansing compositions lies in the retention of the active materials. Although the active may be incorporated into a toothpaste or mouthwash, treatment of the mouth with such products conventionally provides contact of the product

25

with the mouth for a relatively short time (a matter of a few minutes at most), before the product is spat out and/or rinsed out of the mouth. In the relatively short contact time the product has with the mouth, there is

5 insufficient time for the active to absorb into the part of the mouth in which it is required. For example, in a typical brushing with a toothpaste containing zinc, only 17% of the zinc in the toothpaste is actually retained in the mouth after brushing.

10

With creams or gels, a disadvantage of such treatments is that they need to be manually applied and rubbed into the area of the mouth that requires treatment. Such a procedure can be time consuming and awkward to perform

15 effectively in the mouth. Additionally, such treatments generally contain adjuncts other than the actives required for the specific treatment, and as such may be considered wasteful of raw materials.

20

In a very different technical field, the principle of electrostatic spraying of liquid and solid materials is well known. In this technique a formulation to be sprayed is raised to a high electric potential in a spray nozzle to cause the formulation to atomise as a spray of

25

electrically charged droplets. Such electrically charged droplets seek the closest earthed object to discharge

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their electric charge, and this can be arranged to be the desired spray target. Hitherto, electrostatic spraying techniques have been proposed principally for only large-scale industrial and agricultural applications, especially for delivering reactive materials like paints, adhesives and other surface coatings, as well as large-scale delivery of pesticides and other agricultural or

agrochemical formulations. Examples of disclosures in this field include GB-A-1393333, GB-A-1569707, GB-A-2092025, EP-A-029301, EP-A253539 and WO-85/00761, the contents of which disclosures are incorporated herein by reference, and describe proposals for utilising the known principle of electrostatic spraying for delivering particular materials in specific application other than those mentioned above.

- 10 EP-A-224352 suggests the use of an electrostatic sprayer for delivering a pharmaceutically active agent to the eye, to replace conventional ocular treatment using eye drops.

- Also to be mentioned, though of less relevance, is
15 US 4776515, which proposes an electrodynamic fine particle negative ion generator adapted to spray various liquids, particularly water, but possibly also alcohol, perfume, ammonia, liquid medications and surfactants. The object of the disclosed system is to provide an ozone-free mist
20 of negatively ionised liquid particles, (which presupposes that the material to be sprayed is ionizable), and the mist that is produced instantly disperses into an open area in which the apparatus is operated, eg. a room, so that a far-reaching, uniform aerosol is generated which
25 has particular applicability for large public areas such as hospitals, restaurants and offices. Clearly, this system is unsuitable for small-scale personal use and in many of its objects goes directly against the principles upon which a solution to the above mention prior art
30 problems must be founded.

As a result of identifying and appreciating the above problems, prejudices and limitations of the known art, we have now devised a system which enables the principle of

electrostatic spraying to be put to effective use in delivering dentally active materials to the oral cavity, such that apparatus and methods are now provided for such delivery regimes which are technically efficient, cost
5 effective, safe, have widespread consumer applicability and appeal, and which solve or at least ameliorate many, if not all, of the problems associated with the prior art.

Accordingly, in a first aspect the present invention
10 provides a method of delivering one or more dental active materials to the oral cavity, comprising electrostatically spraying the material(s) therein.

In more detail, the method of this aspect of the invention
15 preferably comprises:

(a) providing an apparatus which includes:

- 20 (i) a reservoir containing the dental active material to be delivered which is an electrostatically sprayable form;
- (ii) at least one delivery means in communication with the reservoir;
- 25 (iii) a high voltage generator powered from an electricity source;
- 30 (iv) control means for selectively applying the high voltage from the generator to the or each delivery means;

(b) actuating the control means to electrostatically spray the dental active material(s) from the or each delivery means into the oral cavity at an intended site.

5

In a second aspect, the present invention provides apparatus for delivering one or more dental active materials to the oral cavity, comprising:

- 10 (a) a reservoir for containing the dental or active material which is in an electrostatically sprayable form;
- (b) at least one delivery means in communication
15 with the reservoir;
- (c) a high voltage generator powered from an electricity source;
- 20 (d) control means for selectively applying the high voltage from the generator to the or each delivery means to electrostatically spray the dental active material from the or each delivery means.

25

In a third aspect, the present invention provides, in combination, the apparatus as defined above and an electrostatically sprayable composition consisting or consisting essentially of one or more dental active
30 materials.

According to a further aspect of the invention, there is provided a charged cloud, preferably an electrostatically charge cloud of droplets comprising a dental active

material, which may conveniently be sprayed into the oral cavity.

Having thus defined the main aspects of the present invention, preferred embodiments and various optional features and characteristics thereof will now be described, with reference to the accompanying drawing, in which:

10 Figure 1 is a schematic cross sectional view of one embodiment of the apparatus according to the present invention, which may be particularly useful for local applications of actives in the oral cavity.

15 Figure 2 is a schematic cross sectional view of a further embodiment which can be used for example as a breath freshener.

An advantage of delivery systems according to the present invention is that the dentally active material to be delivered to the oral cavity can be delivered in a neat or relatively concentrated solution; that is to say a solution in water, ethanol or both which is almost saturated with the compounds to be delivered. A principle advantage of the delivery system according to the invention is that once the active ingredients are delivered to the oral cavity, they need not be rinsed and/or spat out.

30 As a result of using a fairly concentrated solution of dental active materials which may be sprayed in accordance with the invention, the composition to be delivered may be done so using ultra-low dosages and flow rates, in contrast to conventional applications of dental active materials from toothpastes or mouthwashes. Suitable and

preferred parameters in the context of this invention are discussed further below.

Preferred dental active materials which may be delivered
5 according to the present invention include essentially
neat or (where necessary) solutions or slurries of the
following materials;

- anticaries compounds, including soluble and sparingly soluble fluoride compounds, in
10 particular: sodium fluoride, potassium fluoride, calcium fluoride, stannous fluoride, magnesium fluoride and disodium monofluorophosphate, and mixtures thereof; as well as other anticaries compounds such as urea, a mixture of sodium
15 fluoride/trimetaphosphate, peptides, casein and casein digests, synthetic calcium hydroxapatite and enzymes;
- antimicrobial agents such as zinc, tin, copper...
20 salts, Triclosan (2',4,4',-trichloro-2-hydroxy-diphenyl ether), sanguinarine, hexetidine, chlorhexidine, allantoin, cetylpyridinium chloride, or mixtures thereof;
- functional biomolecules, such as antibodies and antibody fragments, bacteriocins, bacteriophages
25 enzymes, antibacterial proteins such as histatins, defensins and tissue respiratory factor;
- calculus prevention agents, such as various
30 known chelating agents, for example di- and/or tetra-alkalimetalphosphates, metal salts known to the skilled man for their calculus prevention

effect (eg zinc salts), phosphonates, diphosphonates and polymers such as polyvinylmethylether-maleic anhydride co-polymers;

5

- oral malodour prevention compounds, such as zinc salts and Triclosan;

10

- actives for the treatment of sensitive teeth, such as potassium salts, strontium salts, silver salts, eugenol, varnishes, shellac, formaldehyde and sodium citrate;

15

- improved fluoride delivery vehicles, including flavour oils, gelatin, eugenol (oil of cloves), silicone polymers, and detergents;

- local anaesthetics, such as lignocaine.

20

- Other compounds, including flavour oils, sweetening agents, preservatives, vitamins such as vitamin C and E, colouring agents, anti-inflammatory agents such as substituted salicylanilides, plant extracts, anti-adhesion polymers, whitening agents such as hydrogen peroxide (and other peroxide sources), and antioxidants.

25

Especially preferred dental actives for delivery according to the invention include flavour oils, polymers, organic antimicrobials, and high efficacy antimicrobials such as tin, zinc and Triclosan.

30

Where a solvent is required for the delivery system, preferred solvents are water, ethanol, and mixtures

thereof. Such solvent systems provide the solution to be delivered with the optimal resistivity to be delivered by the delivery system. Other preferred delivery vehicles for the dental active include flavour oils, sorbitol,
5 glycerol, and polyethylene glycols.

Generally there is the essential overall requirement of the dental active material(s) or compositions containing then which are useful in the present invention that they
10 be electrostatically sprayable.

A principal characteristic of such electrostatically sprayable material(s) or compositions which it will usually be necessary (as discussed further below), is
15 their resistivity. Preferred resistivities fall within the range from about 10^1 to about 10^9 ohm cm. Resistivity is measured using standard, conventional apparatus and methods, generally at 25°C.

20 In accordance with the invention, the dental active material(s) or composition(s) containing them may optionally include a suitable amount of one or more resistivity adjusting materials. A suitable amount for a given system may depend upon the type or types of active
25 material used and possibly other spraying parameters and is readily determinable by simple experiment. Suitably, polar substances such as alcohols, eg. ethanol, may be used to lower the resistivity of a given cosmetically active material, whereas non-polar substances, eg. oils
30 and other hydrophobic materials, may be used to increase its resistivity. Generally, any resistivity adjusting agent which is used preferably solubilises or is soluble in, or is miscible with, the dental active material(s) in question. Alternative resistivity adjusting materials

include charged species such as salts, eg. sodium chloride, or a salt conventionally used in buffers in personal products or pharmacological formulations.

- 5 In addition to resistivity, another parameter of the materials or compositions to be sprayed which it may be necessary to carefully select or adjust is viscosity.

10 Neat or substantially neat dental active materials of a wide range of viscosities may be suitable for use in the present invention, but if desired or as necessary one or more viscosity adjusting agents may be included. Examples of such agents include salts, eg. alkali metal or ammonium halides, polymers and conventional thickening materials
15 such as hydroxypropylcellulose, hydroxypropylmethylcellulose, methylcellulose, other cellulose derivatives such as cellulose ether derivatives, polyvinylalcohol, polyvinylpyrrolidone, and optionally cross-linked polymers of acrylic acid and derivatives
20 thereof. As already mentioned, a viscosity adjusting agent which is present as an adjunct material is preferably present in minimal quantities, ie. preferably less than 1% by weight of the total material or composition to be delivered.

25 Viscosity may in fact be used as a parameter to control the rate of delivery of the dental active material to the intended site, as it has been found to have a substantially inverse proportionality relationship with
30 the flow rate of the material or composition when using a wicking delivery means. For example, parameters which may also be so selected and/or adjusted include for example: voltage generated by the high voltage generator and power source, electric field strength in or in the region of the

product delivery means, flow rate of the product to be sprayed from the reservoir to and out of the delivery means, size and configuration of the delivery means itself and construction and properties of any product feed
5 mechanism utilised between the reservoir and the output of the delivery means.

In preferred embodiments of the invention, preferred voltages generated by the high voltage generator from the
10 power source are in the range of from about 2 to about 12 kilovolts, more preferably from about 5 to about 10 kilovolts, even more preferably from about 6 to about 8 kilovolts. The most suitable voltage for a given system may depend upon the product to be sprayed, as well as
15 other parameters, all of which will generally be selected to give an overall optimised system.

Optimum flow rates of product to be sprayed will often depend upon the composition of the product itself,
20 especially upon the concentration of the active ingredient being applied. Also, as already mentioned with respect to viscosity of the sprayable material, a suitable flow rate may be selected depending upon the identity of the dental active and/or habit or needs of a user. By way of
25 example, preferred flow rates in embodiments of the invention are in the range of from about 0.0001 to about 0.01 ml/sec. These flow rates will generally be for a single given product delivery means. In embodiments of the apparatus of the invention which employ a plurality of
30 such delivery means, it may be more appropriate to base the selected flow rate on the overall total flow rate of all the delivery means, in which case the optimum flow rate per delivery means may be correspondingly lower than the above preferred values.

The size and configuration of the one or more delivery means in the apparatus of the invention may be of any suitable form and again may be selected in association with other parameters to give an optimised functioning electrostatic spray delivery system. Commonly the or each delivery means will be in the form of a nozzle, preferably of insulating material such as plastics or various polymers, as it well known in the art.

10 As a result of certain of the advantages associated with the present invention, namely the provision of a charged droplet spray with an ultra-low flow rate, and because the dental active materials to which the invention is particularly directed are only required to be delivered in
15 relatively low dosages, it is a particularly preferred feature of methods and apparatuses in accordance with the invention that there are provided means for providing dosage control so that overdosage of the dental active is avoided. Such dosage control means preferably comprise
20 means for actuating the spraying apparatus for a predetermined period of time. Alternatively or additionally, the dosage control means may comprise means for delivering a predetermined amount of product from the or each delivery means, such as to provide a fixed dosage
25 mechanism with or without control of the spray delivery time. For the above purposes, suitable control circuitry comprising an electronic timer and switch may be included in the apparatus, as may any suitable known metering means which supply a predetermined fixed amount of product from
30 the reservoir to the or each delivery means.

In preferred embodiments of the apparatus of the invention, the or each delivery means is in communication, ie. preferably fluid communication, with the reservoir or

reservoirs (if for example more than one material or composition is desired to be sprayed from the same apparatus or even the same delivery means) by virtue of product feed means. As is well described in the prior art, such feed means may comprise a wick, eg. a porous wick, through and/or over which the product to be sprayed flows before reaching the point of high electric field strength where it is dispersed as a charged spray of droplets or particles. Alternatively the feed means may comprise a hollow conduit through which the composition passes under the effect of capillary action or a low pressure pump.

As is well known in the art, the apparatus according to the invention preferably include a trigger (ie. a manual control means) or alternatively an automatic control means to selectively apply the high voltage from the generator to the or each delivery means to electrostatically spray the dental active into the oral cavity. Any other suitable control means however, eg. which automatically control actuation of the system, may be used, as will be appreciated by persons skilled in the art.

There now follows a description of two preferred embodiments of apparatuses of the present invention, in conjunction with which reference should be had to the accompanying figures 1 and 2.

As shown schematically in the figure 1, the electrostatic spraying apparatus comprises an elongate housing 2 of insulating material eg. a plastics moulding, which contains the various hardware components of the system to provide a lightweight, hand-held unit that is convenient and easy to manipulate and use.

Within the elongate housing 2 are provided the various components of the electrostatic spraying system, comprising the following main elements: power source 12, high voltage generator 14, additional circuitry 16a and 16b, operation control means 20, reservoir 4, product 6 to be sprayed and delivery means 8 and corresponding tip 9 which is well recessed inside the protective end portion 10 of the housing, from which the product 6 is sprayed. Each of these elements will now be described in more detail.

The power source 12 is conveniently a pair of low voltage batteries, such as two conventional 1.5 volt cells as used in small electrical devices such as electronic calculators and watches. The high voltage generator 14 is a transformer which converts a low AC voltage produced by the additional circuitry 16a into a high AC voltage which is then fed to the electrostatic spraying head elements via additional rectifying circuitry 16b. The latter additional circuitry includes for example one or more capacitors and diodes for, among other things, converting the high AC voltage from the transformer 14 to a high DC voltage.

Included as the elements of the electrostatic spraying head are the reservoir 4 containing the product 6 to be sprayed and the product delivery means 8. Electrical contact means 5 are provided to enable the product 6 to be raised to the high electric potential generated by the high DC voltage produced by the electrics of the apparatus. The product 6 is, in this embodiment, a concentrated oil based solution of Triclosan.

In the alternative it may be an aqueous solution of sodium fluoride or zinc salt, the latter zinc solution providing a convenient portable oral malodour treatment. Such a composition however requires modification of the wick
5 employed, to make it suitable for aqueous systems.

The delivery means 8 in the illustrated embodiment is a wick of porous material, eg. a porous polymeric material, through which the product 6 is drawn to its tip 9 by
10 capillary action and/or wetting. At the tip 9 the high electric field strength causes the product to be ejected from the tip, for example at first in the form of a thin ligament, but in any event ultimately as an atomised spray of electrically charged droplets which seek the closest
15 earthed object to discharge their electric charge. In use, the earthed target is the oral cavity, including the tongue, teeth and gums, onto which it is desired to deliver the dental active material.

20 In an alternative preferred embodiment of the apparatus, the tip 9 of the delivery means 8 may be in the form of a crown-like configuration, with the delivery means 8 preferably providing a narrow conduit through which the product 6 is drawn to the nozzle under capillary action,
25 as disclosed in EP-A-0243031, the disclosure of which is incorporated herein by reference. In this arrangement the electric field strength at the plurality of projecting portions of the nozzle is sufficiently large compared with the remaining edge areas of the nozzle to cause the
30 product 6 to be electrostatically projected from the tip of the delivery element 8 at each of those plurality of locations on the tip.

The apparatus illustrated schematically in Figure 1 further included a microswitch 20 which constitutes the control means for actuating the apparatus by applying, when the switch is operated, the high voltage from the electrics to the delivery means. The location of the microswitch 20 in the apparatus is preferably chosen so as to be readily operatable by the user, eg. using a finger, when the apparatus is held in the hand and directed into the oral cavity ready for use.

Figure 2 represents an alternative embodiment of an apparatus according to the invention, designed for example for applying to the oral cavity a breath freshening composition. In this embodiment, which is topologically the same as that described with reference to figure 1, the reference numerals represent the same parts of the apparatus as in figure 1. The major difference between the device of figures 1 and 2 is that whereas the device of figure 1 has an elongate housing with the delivery tip 9 housed deep inside a protective end portion 10 of housing 2, the device of figure 2 has a relatively flat end portion 10 providing no effective protection for tip 9. The shape and configuration of the device of figure 2 are such that the device cannot readily be put into and manipulated inside the mouth.

CLAIMS

1. A method of delivering one or more dental active materials to the oral cavity, comprising
5 electrostatically spraying the material or materials therein.
2. A method according to claim 1, which comprises:
(a) providing an apparatus which includes:
10 (i) a reservoir containing the dental/active material to be delivered which is in an electrostatically sprayable form;
15 (ii) at least one delivery means in communication with the reservoir;
(iii) a high voltage generator powered from an electricity source;
20 (iv) control means for selectively applying the high voltage from the generator to the or each delivery means;
- 25 (b) actuating the control means to electrostatically spray the dental active material or materials from the or each delivery means into the oral cavity at an intended site.
- 30 3. A method according to claim 1 or claim 2 wherein the dental active material(s) is delivered at a rate of from 0.0001 to 0.01 ml/sec.

4. A method according to any of the preceding claims, wherein the high voltage generator of the apparatus generates a voltage of from 2 to 12 kilovolts.
- 5 5. A method according to any of the preceding claims, further comprising providing dosage control means for limiting the amount of dental active material(s) which is delivered.
- 10 6. A charged cloud of droplets comprising a dental active material.
- 15 7. A charged cloud of droplets according to claim 6 herein the charged cloud is electrostatically charged.
8. An apparatus for delivering one or more dental active materials to the oral cavity comprising:
 - 20 (a) a reservoir for containing the dental active material which is in an electrostatically sprayable form:
 - 25 (b) at least one delivery means in communication with the reservoir;
 - (c) a high voltage generator powered from an electricity source;
 - 30 (d) control means for selectively applying the high voltage from the generator to the or each delivery means to electrostatically spray the dental active material(s) from the or each delivery means.

9. An apparatus according to claim 8, further comprising dosage control means for limiting the amount of dental active material(s) which is delivered.
- 5 10. An apparatus according to claim 9, wherein the dosage control means comprises timing means for actuating the control means for a predetermined period of time, and/or metering means for delivering a predetermined quantity of the dental active material(s).
- 10 11. An apparatus according to any one of claims 8 to 10, further comprising product feed means between the reservoir and the or each delivery means.
- 15 12. An apparatus according to claim 11, wherein said feed means is a wick.
13. An apparatus according to any one of claims 8 to 12, wherein the high voltage generator generates a
20 voltage of from 2 to 12 kilovolts.
14. In combination, the apparatus of any one of claims 8 to 13 and an electrostatically sprayable composition consisting of or consisting essentially of one or
25 more dental active materials.
15. An electrostatically sprayable composition consisting of or consisting essentially of one or more dental active materials.
- 30 16. A composition according to claim 15 which has a resistivity of from 10 to 10^9 ohm cm.

17. A composition according to claim 15 or claim 16 further comprising a resistivity adjusting agent and/or a viscosity adjusting agent.

Patents Act 1977

**Examiner's report to the Comptroller under
Section 17 (The Search Report)**

Application number

GB 9226691.5

Relevant Technical fields

(i) UK CI (Edition L) A5B (BZ); B2F (FGB)

(ii) Int CI (Edition 5) A61M, A61K

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

Search Examiner

S I AHMAD

Date of Search

19 APRIL 1993

Documents considered relevant following a search in respect of claims 1-17

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
	NONE	

Category	Identity of document and relevant passages -22-	Relevant to claim

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